

JUL 17 2003

K031893  
page 1 of 2

Special 510(k) Summary of Safety and Effectiveness:  
Line Extension to the Xia Spinal System and the Xia Stainless Steel System

Proprietary Name: Xia Spinal System and Xia Stainless Steel System

Common Name: Spinal Fixation Appliances

Proposed Regulatory Class: Class II

Spinal Interlaminar Fixation Orthosis, 21 CFR 888.3050  
Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060  
Pedicle Screw Spinal System, 21 CFR 888.3070

Device Product Code:  
87 KWP: Appliance, Fixation, Spinal Interlaminar  
87 KWQ: Appliance, Fixation, Spinal, Intervertebral Body  
87 MNH: Spondylolisthesis Spinal Fixation System  
87 MNI: Orthosis, Spinal, Pedicle Fixation

For Information contact:  
Karen Ariemma  
Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
59 Route 17  
Allendale, NJ 07401-1677  
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Date Summary Prepared: May 30, 2003

**Predicate Device Identification**

The Xia Spinal System consists of Monoaxial and Polyaxial Screws, Washer, Hooks, Blocker, Rods, Connectors, Multi-Axial Cross Connectors (MACs), and Staple.

The Xia Stainless Steel System consists of Monoaxial and Polyaxial Screws, Washer, Hooks, Blocker, Rods, Connectors, Multi-Axial Cross Connectors (MACs), and Staple.

**Description of Device Modification**

This submission is intended to address a line extension to both the Xia Spinal System and the Xia Stainless Steel System. The line extension includes a Dual Staple and modified cross connectors. The new components will be used for anterior fixation.

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page 2 of 2**Intended Use:**

The Xia Spinal System and the Xia Stainless Steel System are intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spinal System and Xia Stainless Steel Systems are intended for patients: (a) having severe spondylolisthesis (Grades I-III) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusion using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Spinal System and Xia Stainless Steel Systems are also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Spinal System and Xia Stainless Steel Systems are indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

**Statement of Technological Comparison:**

The subject components share the same intended use and basic design concepts as that of the predicate device. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 17 2003

Ms. Karen Ariemma  
Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
59 Route 17  
Allendale, NJ 07401-1677

Re: K031893

Trade/Device Name: Xia Spinal System and Xia Stainless Steel System

Regulation Number: 888.3050, 888.3060, 888.3070

Regulation Name: Spinal interlaminar fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system

Regulatory Class: II

Product Code: KWP, KWQ, MNI, MNH

Dated: June 17, 2003

Received: June 19, 2003

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

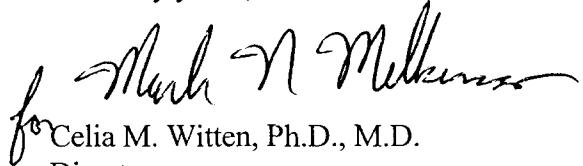
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K 031893

Device Name: Xia Spinal System and Xia Stainless Steel System

The Xia Spinal System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spinal System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Spinal System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Spinal System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_ (Per 21 CFR 801.109)  
(Optional Format 1-2-96)

for Mark A. Melkman  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K 031893

510(k) Number (if known): K 031893

The Xia Stainless Steel System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Stainless Steel System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Stainless Steel System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

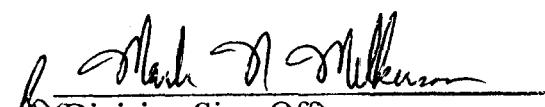
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

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Division of General, Restorative  
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